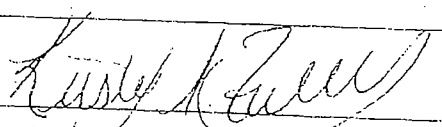
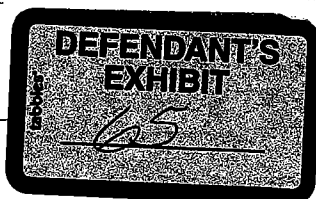

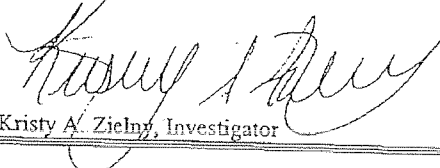


# **EXHIBIT 65**

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969	<small>DATE/ST OF INSPECTION</small> 09/05/2007 - 09/28/2007* <small>FEI NUMBER</small> 2244683	
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> TO: Mr. Apurva Patel, Managing Director, Totowa, NJ		
<small>FIRM NAME</small> Actavis Totowa LLC <small>CITY, STATE ZIP CODE, COUNTRY</small> Little Falls, NJ 07424-5608	<small>STREET ADDRESS</small> 101 E Main St <small>TYPE ESTABLISHMENT INSPECTED</small> Pharmaceutical Manufacturer	
<p>This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.</p>		
<p>DURING AN INSPECTION OF YOUR FIRM I OBSERVED:</p>		
<p><b>QUALITY SYSTEM</b></p>		
<p><b>OBSERVATION 1</b></p> <p>An NDA-Field Alert Report was not submitted within three working days of receipt of information concerning a failure of one or more distributed batches of a drug to meet the specifications established for it in the application.</p> <p>Specifically, a Field Alert was not submitted within three working days of receipt of out of specification results during the stability testing of Carisoprodol, Aspirin and Codeine Phosphate Tablets, 200 mg / 325 mg / 16 mg, Lot 60484A1 at the twelve-month stability test interval. The original out of specification result was received on 8/21/07, results were confirmed as OOS on 8/28/07, but the Field Alert was not submitted until 9/7/07.</p>		
<p><b>LABORATORY CONTROL SYSTEM</b></p>		
<p><b>OBSERVATION 2</b></p> <p>The written stability testing program is not followed.</p> <p>Specifically, the following products were not tested at the 36-month stability test point:</p> <p>Meperidine Hydrochloride and Promethazine Hydrochloride Tablets, 50 mg / 25 mg, Lot 4117A1</p> <p>Dexchlorpheniramine Maleate ER Tablets, 6 mg, Lot 4092A1</p> <p>Methenamine Mandelate Tablets, 10 mg, Lot 4120A</p> <p>Chlordiazepoxide Hydrochloride and Clonidine Bromide Capsules, Lot 3480A3</p> <p>The above listed products were tested at a later date, but the cause for not conducting the testing at the appropriate time was due to incorrect assumptions that the product need not be tested due to changes in expiration dating.</p>		
SEE REVERSE OF THIS PAGE		<small>DATE ISSUED</small> 09/28/2007
<small>FORM FDA 483 (04/03) PREVIOUS EDITION OBSOLETE</small>		
<b>INSPECTIONAL OBSERVATIONS</b>		
<small>PAGE 1 OF 3 PAGES</small>		



DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION	
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969		09/05/2007 - 09/28/2007*	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED		FEI NUMBER	
TO: Mr. Apurva Patel, Managing Director, Totowa, NJ		2244683	
FIRM NAME		STREET ADDRESS	
Actavis Totowa LLC		101 E Main St	
CITY, STATE, ZIP CODE, COUNTRY		TYPE ESTABLISHMENT INSPECTED	
Little Falls, NJ 07424-5608		Pharmaceutical Manufacturer	
<b>PRODUCTION SYSTEM</b>			
<b>OBSERVATION 3</b>			
Written production and process control procedures are not followed in the execution of production and process control functions.			
Specifically, the Standard Operating Procedures "Investigation of Deviations" (SOP # 0033) and "Investigation of Out of Specification Results" (DOI # QC-059) are not followed in that Investigations are not initiated when a deviation or out of specification result is detected and are not closed within 30 days. In addition, interim reports are not always written to document justification for investigations to remain open after each 30 day interval.			
For example:			
a) No investigation for Buspirone HCl Master Blend Lot 70683A was initiated as of 9/25/07 although the blend was placed on hold for unidentified particles discovered in the blend on 9/6/07.			
b) An investigation for low yield of Carisoprodol, Aspirin and Codeine Phosphate Tablets USP 200/325/16mg, Lot 70488A was not initiated when the yield was determined to be <del>low</del> on 7/9/07. The batch record was signed off as reviewed and approved by production management prior to the initiation of the investigation on 7/18/07.			
b) Investigation of Deviation Reports 07-003 and 07-004 were issued on 1/19/07 and 1/29/07, respectively, but were not closed until 5/25/07.			
c) Only one interim report was written for investigation 07-013, which was open from 3/14/07 through 7/21/07.			
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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	
DISTRICT ADDRESS AND PHONE NUMBER 10 Waterview Blvd., 3rd Floor Parsippany, NJ. 07054 (973) 331-4900 Fax: (973) 331-4969	DATE(S) OF INSPECTION 09/05/2007 - 09/28/2007*
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Mr. Apurva Patel, Managing Director, Totowa, NJ	FBI NUMBER 2244683
FIRM NAME Actavis-Totowa LLC	STREET ADDRESS 101 E Main St
CITY, STATE, ZIP CODE, COUNTRY Little Falls, NJ 07424-5608	TYPE ESTABLISHMENT INSPECTED Pharmaceutical Manufacturer
<p>* DATES OF INSPECTION: 09/05/2007(Wed), 09/06/2007(Thu), 09/10/2007(Mon), 09/11/2007(Tue), 09/12/2007(Wed), 09/13/2007(Thu), 09/14/2007(Fri), 09/18/2007(Tue), 09/20/2007(Thu), 09/21/2007(Fri), 09/24/2007(Mon), 09/25/2007(Tue), 09/26/2007(Wed), 09/27/2007(Thu), 09/28/2007(Fri)</p>	
<p>FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:</p> <p> Kristy A. Zielny, Investigator</p>	
<p>RELEASE</p> <p>REVIEWED BY <u>Az</u> <u>5/7/08</u> C.O. DATE</p>	
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